**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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*Ex parte* H. GARRETT WADA, and MATTHEW B. MURPHY

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Appeal 2007-3733
Application 10/613,220
Technology Center 1600

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Decided: January 14, 2008

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Before DEMETRA J. MILLS, ERIC GRIMES, and FRANCISCO PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a system for detecting a component of interest in a biological sample. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

*THE INVENTION*

Detecting a DNA molecule or protein of interest in a biological sample is "of fundamental value in, e.g., diagnostic medicine, archaeology,

anthropology and modern criminal investigation" (Spec. 1). Thus, the Specification discloses "devices, systems, and kits for detecting a component of interest in a complex mixture" (*id.* at 2).

Claims 1-23 are pending and on appeal (App. Br. 2).[1] Claim 1 is representative and reads as follows:

> 1. A system for detecting a component of interest in a sample, the system comprising:
>
> (i) a microfluidic device comprising:
>
> (a) a first microscale channel comprising a gel filled component separation region;
>
> (b) a second microscale channel downstream from the first channel that is fluidly coupled to the first channel, the second channel configured to contain a particle set therein;
>
> (c) a binding region fluidly coupled to or within the first channel;
>
> (d) a source of a component-binding moiety fluidly coupled to the binding region which is capable of binding to the component of interest;
>
> (e) a first detection region within the first channel; and
>
> (f) a second detection region within the second channel which includes a particle stacking region within the second detection region;
>
> (ii) a fluid direction system fluidly coupled to the microfluidic device, which fluid direction system is configured to transport the sample through at least the first and second microscale channels;
>
> (iii) a control system operably linked to the fluid direction system, which control system is configured to instruct the fluid direction system to deliver or transport the sample through at least the first and second microscale channels; and

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[1] Appeal Brief filed February 8, 2007.

(iv) a detection system which is configured to be positioned proximal to the first and second detection regions.

*THE REJECTION*

The Examiner applies the following documents in rejecting the claims:

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|---|---|---|
| Nelson | US 6,007,690 | Dec. 28, 1999 |
| Spence | US 6,540,895 B1 | Apr. 1, 2003 |

The following rejection is before us for review:

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Nelson and Spence. (Ans. 3-5).

*ISSUE*

The Examiner cites Nelson as disclosing "microfluidic devices comprising several alternative embodiments" (Ans. 3). The Examiner contends that several of Nelson's embodiments meet most of the limitations recited in claim 1 for the microfluidic device (*see id.* at 3-4).

The Examiner concedes that Nelson "does not particularly point out a control system linked to the fluid direction system" (*id.* at 4). Pointing out that Spence "teaches cell sorting utilizing microfluidic systems controlled by a computer or microprocessor that control fluid flow," the Examiner contends that one of ordinary skill would have considered it obvious "to modify the teachings of Nelson et al to include a control system to instruct fluid direction as taught by Spence et al because procedures can be programmed using any suitable software that can perform a variety of functions" (*id.* at 5 (citing Spence, col. 15, ll. 5-27)).

Appellants contend that neither of the cited references discloses or suggests all of the limitations in claim 1 (App. Br. 5). Specifically,

Appellants argue that they "are unable to identify any structure taught by Nelson that corresponds to Applicants' claimed 'source of a component-binding moiety fluidly coupled to the binding region'" (Reply Br. 5). Appellants further contend that "Spence is silent with regard to a channel comprising a gel filled component separation region and so cannot teach a source of a component-binding moiety fluidly coupled to a binding region that is fluidly coupled to or within such a channel" (*id.* at 5-6).

The issue with respect to this rejection, therefore, is whether the Examiner has shown that a device having the configuration of features recited in claim 1, including the "source of a component-binding moiety fluidly coupled to the binding region," would have been obvious to one of ordinary skill in the art.

*FINDINGS OF FACT*

1. Claim 1 recites a system having the following components:

(i) a microfluidic device having a specified arrangement of two channels and several regions;

(ii) a fluid direction system fluidly coupled to the microfluidic device, the fluid direction system being configured to transport a fluid sample through the two channels;

(iii) a control system operably linked to the fluid direction system, the control system being configured to instruct the fluid direction system to transport the sample through the two channels; and

(iv) a detection system configured to be positioned proximal to first and second detection regions in the microfluidic device.

2. Claim 1 requires the microfluidic device component to have:

(a) a first microscale channel having a gel-filled region for separating components within a sample;

(b) a second microscale channel downstream from the first channel, the second channel being fluidly coupled to the first channel and also configured to contain a particle set;

(c) a binding region which is fluidly coupled to the first channel, or which is within the first channel;

(d) a source of a component-binding moiety fluidly coupled to the binding region, the component-binding moiety being capable of binding to a component of interest;

(e) a first detection region within the first channel; and

(f) a second detection region within the second channel, the second detection region including a particle stacking region.

3. Because the "source of a component-binding moiety . . . capable of binding to the component of interest" must be "fluidly coupled to the binding region," we interpret claim 1 as requiring the "source" to be a separate structure from the binding region. This interpretation is consistent with the Specification, which discloses a particle well 112, fluidly coupled to binding channel 110 (Spec. 12; *see also* Figure 1). The Specification discloses that the "particle set is released from particle well 112 into binding channel 110. The particle set with the components [of interest] attached or adsorbed onto the particle member types is then directed to detection region 114, where the particle member types of the particle set are optionally stacked" (Spec. 12; *see also* Figure 1).

4. Nelson describes microfluidic devices useful in separating and detecting compounds of interest in a number of applications, including "high throughput screening, for genomics and pharmaceutical applications such as gene discovery, drug discovery and development, and clinical development; for point-of-care in vitro diagnostics; for molecular genetic analysis and nucleic acid diagnostics; for cell separations including cell isolation and capture; and for bioresearch generally" (Nelson, col. 2, ll. 61-67). Nelson's devices comprise "at least an enrichment channel and a main electrophoretic flowpath . . . . The enrichment channel serves to enrich a particular fraction of a liquid sample for subsequent movement through the main electrophoretic flowpath" (Nelson, col. 2, ll. 48-53).

5. Nelson discloses a number of elements that correspond to claim 1's "component-binding moiety." Specifically, Nelson discloses that the enrichment channel can contain component-binding materials such as affinity adsorbents, metal chelating agents, Protein G, or antibodies, which can be bound to matrices of insoluble particles, or be membrane-bound (*see* Nelson, col. 5, l. 12, through col. 6, l. 53). Nelson discloses an example in which antibody-coated magnetic beads are used to bind to desired targets in the enrichment zone (*id.* at col. 21, l. 13, through col. 22, l. 13 (Example 2)). Nelson also exemplifies using magnetic beads to bind DNA in the enrichment zone (*id.* at col. 22, l. 15, through col. 23, l. 54 (Example 3)).

6. Nelson also discloses that, in certain embodiments, "affinity zones" can be placed in the main electrophoretic path to capture components of interest (Nelson, col. 17, ll. 9-33; col. 18, ll. 28-32; *see also* Figures 16 and 18). The affinity zones may contain the DNA-specific or protein-specific binding moieties similar to those used in the enrichment channel (*id.* at col.

17, ll. 33-47). Nelson does not disclose a separate reservoir or "source" for the component-binding moieties in either the enrichment channel or the main electrophoretic flowpath.

*PRINCIPLES OF LAW*

> As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):
>
> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, "*there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

*ANALYSIS*

We agree with Appellants that the Examiner has not explained where or why the cited references disclose or suggest a microfluidic device having a "source" for the component-binding moieties, wherein the source is separate from a binding region fluidly coupled to or within the first channel.

We note, as pointed out by the Examiner, that Nelson discloses the use of particle-borne component-binding moieties in different parts of its various microfluidic devices (*see* Findings of Fact 6 and 7, above).

However, Nelson's component-binding moieties are intended to remain in either the enrichment zone or affinity zones, with the component of interest being eluted therefrom (*see, e.g.,* Nelson at col. 21, l. 13, through col. 22, l. 13 (Example 2); col. 22, l. 15, through col. 23, l. 54 (Example 3)). Thus, since Nelson's component-binding moieties do not appear to move from their designated zones within the device, we see no apparent specific reason why a person of ordinary skill would have given Nelson's device a separate source of material to replenish the component-binding moieties. Moreover, we do not see any clearly articulated reasoning from the Examiner explaining why one of ordinary skill viewing the cited references would have considered it obvious for Nelson's device to contain a separate source, or reservoir, for the component-binding moieties.

It is well settled that the "Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art." *In re Lowry*, 32 F.3d 1579, 1582 (Fed. Cir. 1994). Because the Examiner has not explained why every limitation in claim 1 would have been obvious to a person of ordinary skill in the art, we agree with Appellants that the Examiner has not made out a case of prima facie obviousness. We therefore reverse the Examiner's obviousness rejection of claims 1-23.

REVERSED

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